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METALS

Superelastic Nitinol for Medical Devices

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Superelastic nickel-titanium (Ni-Ti), or nitinol, alloys are becoming integral to the de a variety of new medical products. The enormous elasticity of these alloys is the mo dramatic advantage afforded by this material, but by no means the only or most im one. Also discussed in this paper are features such as biocompatibility, kink resistan constancy of stress, physiological compatibility, shape-memory deployment, dynami interference, and fatigue resistance. Each of these properties is discussed and highli through examples of medical products including stents, filters, retrieval baskets, anc surgical tools.

Superelasticity refers to the unusual ability of certain metals to undergo large elastic deformation. Although the term is used synonymously with pseudoelasticity, we adh the definition that pseudoelastic alloys need only show nonlinear unloading behavior whereas superelastic alloys must exhibit an inflection point. An inflection point in the unloading behavior indicates the presence of an unloading plateau, or a strain range approximately constant stress. As we will see, this is an important distinguishing fea medical applications. While many metals exhibit superelastic effects, only Ni-Tibasec appear to be chemically and biologically compatible with the human body. Although number of Ni-Ti ternary alloys have been introduced, none has been objectively sho superior to simple binary Ni-Ti with between 50.6 and 51.0 atomic percent nickel.

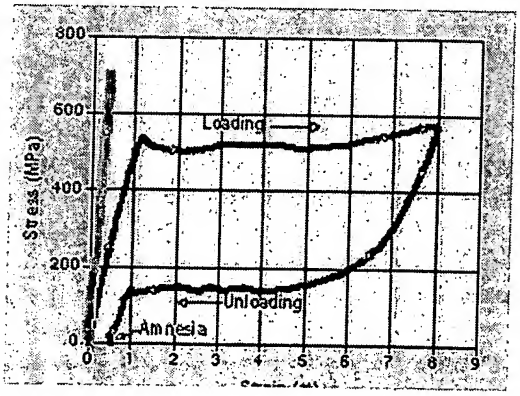

Figure 1. Stress-strain curve for a Ti-Ni alloy atomic percent Ni) tested at 10°C above its temperature. A typical elastic loading/unloa curve for stainless steel is shown in light gra

The stress-strain behavior of superelastic nitinol is illustrated in Figure 1. The detail mechanistic origins of superelasticity have been discussed extensively elsewhere.[1,2] most superficial advantage of superelastic alloys is that up to 11% springback or ela realized, as compared with 0.5% in the most commonly used medical material, stair steel. Of course, superelasticity only occurs over a relatively narrow temperature ra above the austenite finish (Af) temperature--optimum performance is found at the A temperature, and performance steadily deteriorates until the martensite deformatio temperature, at which point all indications of superelasticity have vanished. It shoul noted that many designs have complex geometries and strain distributions, and tha increases with strain. For example, an 8% strain will increase Af by approximately 1 Thus, optimum superelasticity requires that one completely understand the strain to the part will be subjected.

Strengthening the alloy--through a combination of cold work, aging, and annealing-- provides it with optimum performance over approximately a 40°C window, starting a temperature. Still, the functional temperature range is too narrow for most industria consumer applications--automobile springs, for example, generally require elasticity 30° to 200°C. Moreover, the stiffness of a superelastic device changes with tempera according to the Claussius-Clapeyron equation, at a rate of approximately 48 MPa/°(variability of superelasticity with temperature is, by far, the factor most limiting to it general use. Fortunately, mammalian bodies have a relatively constant temperature suited to the use of superelasticity. Furthermore, the 37°C temperature of humans i chance, easily achieved in Ni-Ti without having to go to brittle Ni-rich alloys, or to ve Ti-rich alloys. Thus, the vast majority of successful superelastic applications are of a nature.

ADVANTAGES OF SUPERELASTICITY IN MEDICINE

Material selection is seldom based on a single attribute, but rather on a combination several. Similarly, the tremendous elasticity of nitinol is only one of the many uniqu favoring its use. To highlight the value of superelastic nitinol to the medical

industry, the following 10 specific device characteristics will be discussed and illustra the design of a range of medical devices: elastic deployment, biocompatibility, kink resistance, constancy of stress, physiological compatibility, thermal deployment, dy interference, fatigue resistance, hysteresis, and MRI compatibility. Some of these pr such as elastic deployment, are obvious to designers, whereas others, such as dyna interference and hysteresis, are not. Still, all provide potentially important grounds f application of nitinol.

ELASTIC DEPLOYMENT

Figure 1 compares typical stress-strain curves for stainless steel and nitinol. The mo apparent difference is that elasticity, or "springback," is some 20 times greater in ni than in stainless steel. A large variety of products are now on the market that use th particular design feature, but perhaps the newest and most interesting is the atrial s defect occlusion system (ASDOS) (Osypka Medizintechnik, Rheinfelden, Germany).[3] device is the first to allow nonsurgical repairs of occlusions, or holes, in the atrial wa heart. At the time of writing, at least five procedures have been published, treating ranging in diameter from 20 to 35 mm. A transcatheter method is used with the ent procedure conducted through two catheters, in this case 10 french (~3.5 mm) in dia

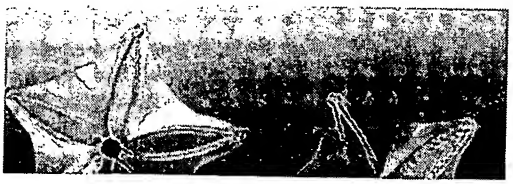

Figure 2. The atrial septal-defect occlusion c used to seal holes in the heart wall. Figure 2 the two umbrella-shaped patches that are p on either side of the defect. Figure 2b shows installed halves, screwed together, after pos

via two 10-french catheters and a guidewire

The actual device comprises two small umbrellas consisting of five nitinol wire loops supporting webs of microporous polyurethane (see Figure 2a). The two umbrellas ar into the body while folded into two catheters, and are positioned one each on either the defect area. A guidewire passing directly through the hole is used to ensure that catheters and umbrella devices are positioned correctly. Once positioned, the umbre pushed forward from their catheters and screwed together using a special torquing (The resulting sandwich forms a patch, occluding the atrial defect. Available umbrella diameters range from 20 to 65 mm. Although it is too early to convincingly evaluate success of this particular product, it illustrates well the concept of elastic deploymen other known metal would survive such an application.

The compliance, or elasticity, of an engineered component depends of course on des well as on the inherent elasticity of the material used. For example, one can increas compliance of a coil spring by adding coils, but this would increase weight and size. properties dictate the total elastic energy stored in the device, while design can only how one partitions the total stored elastic energy of a given amount of material (fav either force or motion). The use of nitinol allows one to design stiffer, more compact more elastic devices by increasing the elastic storage by a factor of nearly 10.

To highlight this, we can look at the Homer Mammalok (Mitek, Westwood, MA), whic radiologists use to "mark" the location of a breast tumor. This device consists of a 0 diam nitinol wire hook and a stainless-steel cannulated needle.[4] The wire hook is wit into the needle cannula, and the cannula inserted into the breast and adjusted until end is verified to be at the site of the tumor. The hook is then pushed out, reforming hook configuration, with a radius of 9 mm. The device can be withdrawn, repositione redeployed as required until the position has been correctly marked for the surgeon. inside the cannula, the strain in the hook is estimated to be in excess of 8%--far mo can be obtained with stainless steel. The same device made from stainless steel wou require a reduction in the wire diameter from 0.40 to 0.05 mm, assuming the hook geometry is to remain fixed. Such a fine wire would be far too flimsy to anchor the h effectively, and could allow inadvertent and undetected transection. Alternatively, a stainless-steel wire of the same 0.40-mm diam could only form a hook of 50-mm ra contrast to the 9-mm radius possible with nitinol. In either case, the hook would mo again fail to firmly hold position.

Endoscopy is another field that has taken advantage of elastic development.[5] As the of endoscopic procedures increases, so does the need for increasingly complex toolin which must pass through a narrow trocar. Superelasticity allows one to pass a rathe complex instrument through a straight trocar, and enables the instrument to elastica return to the deployed configuration once through. Instruments include suture passe retractors, graspers that operate at right angles to the trocar, and retrieval bags. Sin surgical graspers and scissors can be designed without hinges and other complex pa make cleaning and sterilization difficult or impossible (an example will be introduced Figure 8).

BIOCOMPATIBILITY

Nitinol alloys contain more nickel than does their primary competitor, 316L-grade st steel. This rather obvious statement has little meaning to metallurgists, but unfortun entirely too much meaning to nonspecialists, who recognize that nickel itself is consi toxic. As nitinol oxidizes, it forms a TiO_2 layer, with small islands of pure nickel on th surface, or, depending on the treatment, with no nickel present at the surface.[6] Pola testing in Hank's solution has repeatedly shown that nitinol is chemically more stabl less corrosive than stainless steel, but less stable than pure titanium.[7] Extensive in v testing and experience indicates that nitinol is highly biocompatible--more so than s

steel. Nitinol implants exist in dentistry, orthopedics, and many other branches of m with large numbers of permanent implantations reported in Japan, Germany, China, Russia, dating back to the early 1980s.[8] Most significantly, FDA has cleared the way sale of the first Class III nitinol implant for use in the United States, specifically the vena cava filter, developed by Nitinol Medical Technologies (Boston, MA) (see Figure has similarly approved the Mitek bone anchor system, another permanently implant nitinol device.

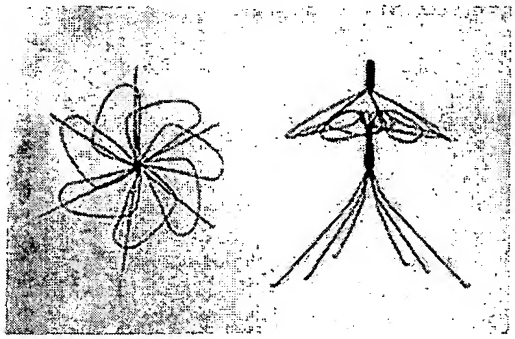

Figure 3. A Simon filter, shown in longitudin transverse views of the deployed state.

A detailed discussion of biocompatibility and all its nuances is certainly beyond the s this article, and readers are referred to several reviews of the field.[8,10] One should b cautioned, however, to carefully observe testing and material conditions before relyi published information, as a great deal of the literature is inadequate in defining star chemistries, thermomechanical treatments, and, most importantly, surface treatmer work on nitinol biocompatibility must be performed before it can be firmly establishe how biocompatible the material is, and how performance can be optimized. Still, reg biocompatibility issues, it is clear that nitinol will outperform stainless steel in most environments.

KINK RESISTANCE

For the most part, nitinol wires cannot be kinked. To some extent, this design prope stems from the increased elasticity cited above, but it is even more a result of the sl the stress-strain curve. When strains are locally increased beyond the plateau strain stresses increase suddenly. This causes the incremental strain to partition to the are lower strain, instead of increasing the peak strain itself. Thus kinking, or strain local is prevented by creation of a more uniform strain than would be realized in a conver elastic-plastic material.

The first applications to take advantage of this feature were angioplasty guidewires, must be passed through tortuous vessel paths without kinking. Even very small perr bends in the wire cause "whipping" and destroy its ability to be steered. The ASDOS procedure described earlier, for example, employs nitinol guidewires to place the cat correctly. There can be little doubt that nitinol has played a key role in the success c angioplasty procedures.

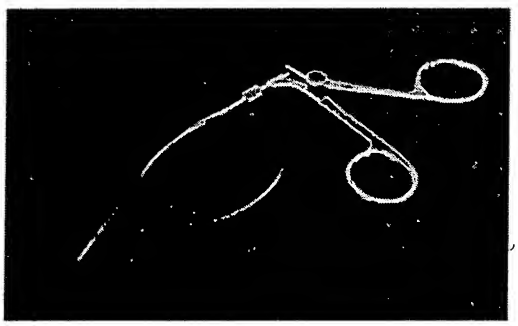

Figure 4. A 1-mm-diam urological grasper (I Tuttlingen, Germany) demonstrates kink res The shaft comprises a nitinol wire concentric placed in a nitinol tube; the distal end is a h stainless-steel grasper, which opens to an approximately 90° included angle.

More recently, retrieval baskets have used nitinol kink-resistant shafts along with a

superelastic basket to retrieve stones from kidneys, bladders, and bile ducts. Perhaps newest and most interesting application is in extremely small-diameter instruments. example, the 1-mm-diam grasper depicted in Figure 4 is composed of a very-thin-w nitinol tube with a nitinol wire inside. Together, they are able to be bent around radi than 3 cm without kinking, and still allow for opening and closing of the distal grasp without increased resistance. Stainless-steel or other metallic instruments would kin destroyed by even very slight mishandling, whereas the nitinol device continues to c smoothly even while bent around tortuous paths.

CONSTANCY OF STRESS

Another important feature of superelastic materials is that their unloading curves ar over large strains. Thus, the force applied by a superelastic device is determined by temperature, not by the strain as in conventional Hookian materials. Because body temperatures are substantially constant, one can design a device that applies a cons stress over a wide range of shapes.

The orthodontic archwire was the first product to take advantage of this property. S steel and other conventional wires are tightened by the orthodontist--often to the pc causing pain. As treatment continues, the teeth move and the forces applied by stai steel quickly relax. This causes treatment to slow, retarding tooth movement. Retigh by the orthodontist recycles the process, with only a narrow optimum treatment per contrast, nitinol wires are able to move with the teeth, applying a constant force ove broad treatment time and tooth position. Different grades of wire stiffness are availa allowing the orthodontist to "program" the stress and ensure that treatment will con properly, with fewer visits and less pain. Nitinol archwires were introduced in the lat we estimate that over 30% of the archwires used today are nitinol. Another popular application is superelastic eyeglass frames--the first successful nitinol consumer pro

PHYSIOLOGICAL COMPATIBILITY

Stainless steel, titanium, and other metals are very stiff relative to biological materi yielding little if at all in response to pressures from surrounding tissue. The extraord compliance of nitinol clearly makes it the metal that is most similar mechanically to biological materials. This improved physiological similarity promotes bony ingrowth a proper healing by sharing loads with the surrounding tissue, and has led to applicati as hip implants, bone spacers (see Figure 5), bone staples, and skull plates. This lat application is particularly interesting in that it utilizes porous nitinol, which further p the advantages of the material, particularly bony ingrowth.[11] Combustion synthesis- using the heat of fusion to "ignite" the formation of Ni-Ti from nickel and titanium--h shown to be an effective way of producing a porous "sponge" of nitinol, with densitie 40 to 90%. The sponge maintains superelastic and shape-memory properties, has a mechanically reduced modulus of elasticity, accelerates bony ingrowth, and offers in adhesion to surrounding tissue. The application of these particular devices was pione Russia, and warrants a good deal more attention than it has thus far received in the States.

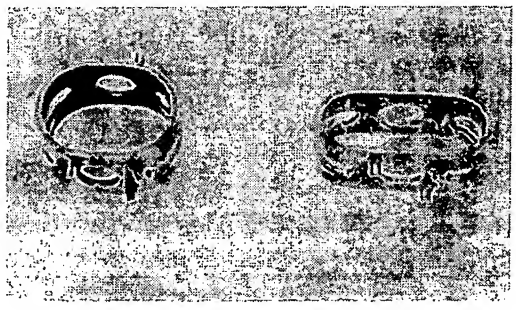

Figure 5. Spinal vertebrae spacer shown in t martensitic state (left) and deployed supere state (right). The characteristics of nitinol pr more rapid recovery due to the similarity of mechanical properties between the implant surrounding tissue.

It should be noted, however, that the physiological compatibility discussed here cor price: calculational complexity. Conventional metals are linearly elastic, and readily themselves to both analytical and finite element analysis (FEA) methods. Nitinol, lik biological materials, is much more difficult to model: not only is its behavior nonline there is a hysteresis, a strong temperature dependency, and a permanent set. To m matters worse, the latter two properties are strain-dependent. A great deal of work currently under way to improve the applicability of modeling methods to these type materials, but much more is needed. As yet, the authors are unaware of a single FE package that is able to deal with all of the above characteristics. Given that FEA is b an important tool for designers and a required element in FDA submissions, we thin this is an area warranting (but not currently receiving) substantial R&D funding.

THERMAL DEPLOYMENT

Another unique attribute of superelastic devices is that they can be deployed using t shape-memory effect. One example is the vena cava filter discussed earlier. The de received by the physician preloaded in a catheter and in its martensitic state. Flushi chilled saline solution through the catheter keeps the device in the martensitic phas is positioned to the deployment site. When released from the catheter, the device is by its warmer surroundings, recovers its "preprogrammed" shape, and becomes a superelastic device. The precise moment at which the device becomes superelastic i clear nor important--very likely this occurs before it is fully released from the cathet chilled saline only acts to reduce the forces applied by the filter against the catheter making deployment easier. It is proper to consider the device to have completed the memory effect when heated above A_f, even when the filter is still fully constrained w catheter, since the equilibrium shape of the device has already been recovered.

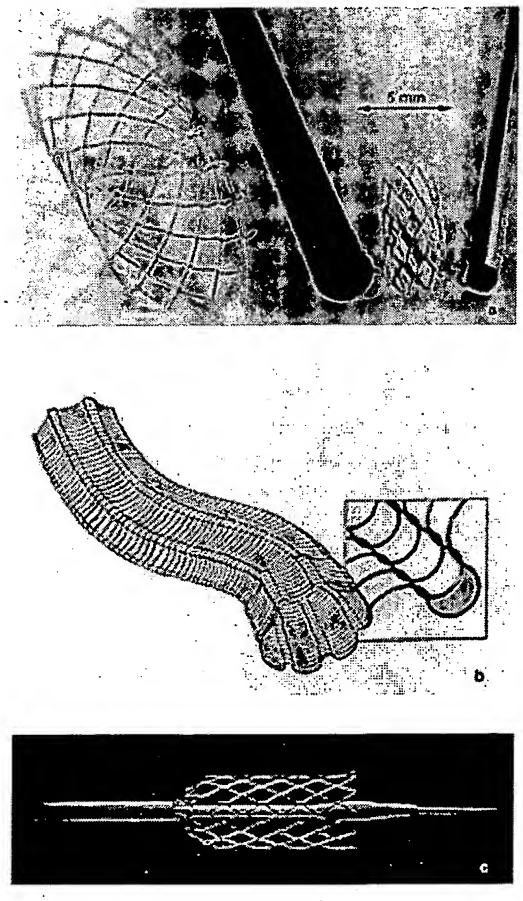

Figure 6. Stents made from nitinol tubing (a receiving a great deal of interest, though wi stents, such as the Microvasive device show are already in use in the United States. Dep of an Angiomed stent (from tubing) is show

The most celebrated superelastic medical devices are self-expanding stents, used to the inside circumference of a tubular passage such as an esophagus, bile duct, or bl vessel (see Figure 6). Probably the most interesting area of application is in the

cardiovascular system, as a follow-up to balloon angioplasty. The placement of a ste been shown to significantly decrease the propensity for restenosis. Like the vena ca these devices are generally permanent implants, deployed through a catheter using shape-memory effect. Even in the case where no chilling is done to assist deployme should consider such devices to be thermally deployed since their equilibrium shape restored by warming to body temperature. Cardiovascular stents currently available United States are made of stainless steel, and are expanded against the vessel wall plastic deformation caused by the inflation of a balloon placed inside the stent. Nitin stents, on the other hand, are self-expanding--instead of being deformed to the ves diameter, they expand by simply returning to their equilibrium, or nondeformed, sh Self-expanding stents are now available in Europe, and, for certain applications, in t United States. Nitinol stents can be made from wire, laser-cut sheet, or tubing. Bec overlaps and irregularities can lead to thrombicity, the most promising devices appe those cut from tubing. Of course, one might cut the expanded or the contracted sha depending on the specific design requirements. Stents are also made from sheet th either welded or mechanically joined into a cylinder after cutting. Typically, the diam ratio of the two states is between 300 and 600%. Surface finish is very important to thrombicity and biocompatibility, and plays a key role in device production.

Anticipated advantages of nitinol stents over current balloon-expandable stents incl greater resistance to crushing in exposed vessels (such as the femoral or carotid art lower bending stresses when situated in tortuous paths, more flexible delivery syste ability to scaffold cross sections other than circles, and the elimination of acute reco certain that nitinol will become the preferred material for many devices, but only tim tell if self-expanding stent technology will indeed spearhead the next generation of interventional treatment, as many physicians and device manufacturers believe.

DYNAMIC INTERFERENCE

Stents benefit from another important feature of superelasticity: dynamic interferen illustrate this, compare a self-expanding nitinol stent with a balloon-expanded, stain steel stent. Following balloon expansion, the balloon is deflated, causing the stent to back towards its smaller, undeformed shape. This type of loosening is called acute springback, and is clearly undesirable. In order to fill a 5-mm lumen, the stent migh to be expanded to 6 mm so that it springs back to 5 mm. This has the potential to d the vessel, and can lead to restenosis. In contrast, the nitinol stent expands directly preconditioned diameter, with no recoil. After deployment, it continues to gently pus outward against the vessel wall, helping to prevent undesirable changes in position movements in the vessel. Moreover, it will try to fill an oblong or irregularly shaped section, whereas a balloon-expanded stent will always adopt the round shape of the

Dynamic interference also means that there will be a permanent force acting in the direction, even if the vessel should increase in diameter over time. Though this may beneficial in maintaining the location of the stent in the vessel, it remains unclear wh there will be long-term side effects. It is possible that this continuous opening force cause irritation, restenosis, or undesirable creep effects. Current designs try to mair force at very low levels.

FATIGUE RESISTANCE

Because of the unusual way that nitinol deforms, it has a fatigue behavior that is qu atypical of metals in general. Fatigue environments can be divided into two distinct strain controlled and stress controlled. The former group describes environments in device is alternately deformed between two set shapes, while the latter describes th influences of cyclic loading. To illustrate the difference, compare the fatigue behavio rubber band and a loop of steel wire. In a stress-controlled environment, the steel s far longer than does the rubber band. In a strain-controlled environment (e.g., alter stretching and releasing), the rubber band will certainly outperform the steel.

Nitinol is much the same: in strain-controlled environments it will dramatically outpe conventional metals. In stress-controlled environments, however, it may well fatigue Practically speaking, most fatigue environments in the body are a combination of th conditions, making it difficult to make summary judgments concerning fatigue. In ge the very compliant nature of biological materials tends to place them in the directior strain-controlled fatigue, where nitinol will excel.

One example of an obvious strain-controlled application is in pacemaker leads, whicl a conductive metal that can survive very high numbers of flexing motions without bi Research on candidate materials has shown that nitinol has superior strain-controlle properties. Certainly a great deal of fatigue testing of stents is being done; although results have been published, it does appear that nitinol performs at least as well as steel.

HYSTERESIS

Stresses applied by superelastic components are path-dependent: that is, the stress applied by a superelastic device are likely to be more dependent upon whether one i loading or unloading than on the position of the device itself. This biased stiffness is illustrated in Figure 7, which charts the expansion of a stent. A superelastic stent sh provide only a very light outward force against a vessel wall, and at the same time t resistant to crushing--compliant in one direction, and stiff in the other. This is a very important feature in stent design. As pointed out earlier, opening forces are "live," a forever continue to act to open the lumen. These opening forces must be very low t damage (through creep) of the vessel wall. On the other hand, it is important to hav device that resists the forces tending to close the lumen. Nitinol can satisfy both of t conditions. Also note that, if the stent is later reexpanded to a larger diameter, the f circle B in Figure 7 will be displaced to the left, but the stiffness will remain the sam

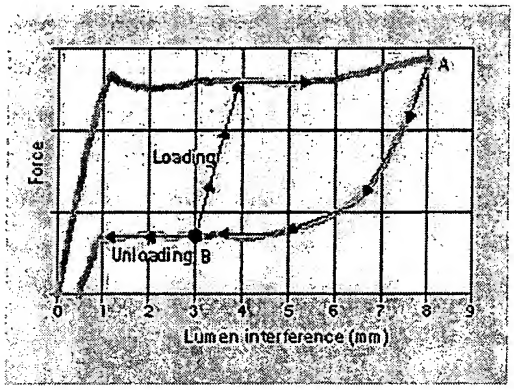

Figure 7. Priniciple of biased stiffness illustra stent. The gentle pressure against the vesse controlled by the unloading arrows, but recl the vessel is resisted by the stiffness indicat the loading arrows.

MRI COMPATIBILITY

Nitinol provides a very clear, crisp MRI image. Figure 8 shows an MRI image of a gra used in gall bladder surgery, together with a matching photograph of the same end. identical grasper made from stainless steel would be completely unrecognizable. Alt there are no commercially available products that take advantage of this feature, it great potential importance, particularly with the advent of open-MRI procedures. Applications for needles and instruments are currently being explored.

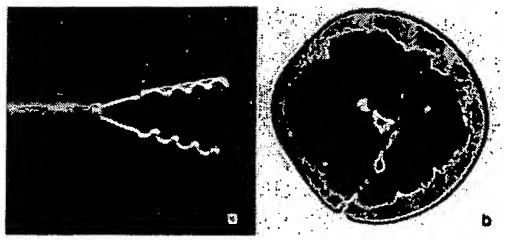

Figure 8. A nitinol grasper, designed for end gall bladder surgery, is shown optically (a) a MRI image while testing in a grapefruit (b).

CONCLUSION

Nitinol alloys provide a unique range of characteristics not found in any ohter materi combination of properties makes them particularly interesting for devices used in interventional procedures. Self-expanding stents, for example, benefit from thermal change for deployment, superealasticity for shape recovery after deformation, dynai interference for perfect fit, and hysteresis for biased stiffness. Moreover, nitinol allo biocompatibility, magnetic-resonance visibility, and fatigue resistance.

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